Testimony of

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Concerning

Bovine Spongiform Encephalopathy (aka "Mad Cow Disease): Are Our Precautions Adequate?

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Mr. Chairman, I am Dr. Will Hueston and I am the Associate Dean of the Virginia-Maryland Regional College of Veterinary Medicine. I am here today to provide testimony based on 12 years of professional experience with bovine spongiform encephalopathy (BSE), commonly referred to as "Mad Cow Disease".

For the benefit of the committee, I have had the privilege to serve on both the US and the UK scientific Advisory Committees on spongiform encephalopathies, so that I can compare the US precautions to the situation that has evolved in Europe over the past 15 years.

I am pleased at the opportunity to present testimony before this committee and briefly share my thoughts on the adequacy of the current US precautions.

Emergence of New Diseases

New animal diseases emerge as a natural response to changes in disease agents, their animal hosts, and the environments in which they live. Discovery of new diseases is a regular occurrence throughout the world. Therefore, the emergence of new diseases such as BSE is to be expected and we must be prepared to respond to each new discovery.

Foreign Animal Disease Surveillance and Emergency Response

The disease BSE was first discovered in 1986 in the UK through the cooperation of a concerned animal producer, an astute veterinarian and a dedicated laboratory scientist. Investigation of the cause of the disease in 1987-1988 identified animal feed containing rendered animal protein (meat and bone meal) as the source of the disease exposure. Therefore, BSE can be described as a common source feedborne epidemic. The most likely origin of BSE appears to be the sheep disease scrapie, a similar spongiform encephalopathy that is widespread in the UK. The first precaution taken to prevent BSE in the US was the training of Federal and state veterinarians and strengthening laboratory diagnostic capabilities so that the disease could be identified quickly should it occur.

Exclusion of Foreign Animal Diseases Through Import Bans

The second step taken to exclude BSE from the US was a ban on the importation of potentially infected animals and animal products. Importation of affected animals (cattle and other ruminants) and contaminated products of animal origin such as meat and bone meal represent the greatest risk for the introduction of BSE to the US. The US initiated bans on the importation of live cattle and cattle products after the UK announced the results of their epidemiology investigations of the new disease BSE. These bans were based on scientific evidence concerning the nature of the disease and its major routes of transmission.

Scientific risk analysis

A risk analysis assessing the potential for BSE occurrence in the US was initiated in 1989 immediately after the import bans were put in place. The risk analysis addressed the question of whether BSE would occur in the US, and if so, whether the US would expect to see an epidemic of the magnitude of that unfolding in the UK. Serendipitously, the risk analysis identified that very few cattle (a total of 496) and very little meat and bone meal (<20 tons) had been imported from the UK and Ireland around the time of the emergence of BSE (1981-1989). Furthermore, major differences were identified in the livestock demographics and cattle industry structure between the US and the UK. The risk analysis results concluded that while the possibility of a case of BSE in the US could not be completely excluded, the likelihood of an epidemic of the magnitude of that seen in Great Britain was remote. The risk analysis also identified specific high risk populations of cattle where the disease would be expected to occur first, if it occurred at all in the US. The risk analysis process helps identify the most important precautions necessary to prevent BSE from occurring in the US.

Targeted surveillance of high risk populations

Identification of BSE depends on the testing of brain material from cattle. No blood test or live animal diagnostic test is currently available. BSE has a very long latency period so that infected cattle do not show clinical signs of the disease until 3-5 years after exposure to the BSE agent in their feed. The disease can only be diagnosed close to or after the clinical signs appear. Therefore disease surveillance must be focused on older animals which have both the potential for exposure and sufficient time for the disease to develop. The risk analysis helped identify specific high risk populations for BSE such as the cattle imported from the UK and older dairy cattle which had been fed meat and bone meal in the US. Therefore, the BSE surveillance program in the US was targeted toward these high risk cattle populations beginning in 1990.

Risk communication and education

Training of veterinarians and educating of producers began immediately after the British identification of this new disease and the results of the initial epidemiologic investigation. US government veterinarians were sent to the UK to learn more about the disease and British experts were invited to the US for consultations. Extensive educational efforts accompanied the risk analysis process. Futhermore, education of animal owners and veterinarians was and is a key component of the ongoing surveillance program.

Guidance to manufacturers

The incorporation of infected cattle tissues into biologics or medical devices represents another potential route for the transmission of BSE. Consequently, the Food and Drug Administration issued a series of guidance documents to manufacturers concerning the risks associated with BSE and the safe sourcing of raw materials of bovine origin.

Industry initiatives

As the epidemiology of BSE became clear, producer groups and industry took voluntary initiatives to reduce the potential for BSE occurrence in the US. The rendering industry took steps to reduce the use of sheep potentially affected with scrapie as raw material for the production of rendered animal protein, such as meat and bone meal. Further, many of the animal industries inaugurated education campaigns, urging producers to assist in the identification of high risk cattle for the surveillance program. Finally, the cattle industry played a critical role in helping to purchase and destroy many of the cattle imported from the UK which represented the greatest risk for the occurrence of BSE in the US.

Additional enhancements to surveillance

The targeted surveillance of high risk cattle populations was expanded to include non-ambulatory cattle (downers) in 1993 as a further step to identify BSE if it existed in the US. Additionally, a second diagnostic test, immunohistochemistry (IHC) was added to the surveillance system to augment the histopathology used to test brains. The US was the first country to implement IHC testing as part of the regular surveillance system. Throughout the 90s, the numbers of high risk cattle screened for BSE grew annually. The US developed the most extensive surveillance system of any country in the world outside of Europe where the BSE epidemic was centered.

Feed bans to bar the potential for recycling of infectivity

Upon the recognition that the BSE agent was associated with a human disease, variant Creutzfeldt-Jakob Disease (vCJD), efforts were initiated to remove ruminant-derived meat and bone meal from US cattle feed. The cattle producers initiated a voluntary program to exclude ruminant meat and bone meal and subsequently, the FDA promulgated a rule banning the feeding of most mammalian proteins to ruminants. The ban was science-based, targeting the feed ingredients that would be of highest risk for transmitting BSE should the disease be identified in the US.

Extension of import bans

Recognition of the BSE risk for humans and the spread of BSE in Europe led to expansion of the import bans placed on cattle and cattle products from all of Europe. Extension of the bans further reduced the likelihood of potentially infected materials entering the US.

Adequacy of current precautions

Since the first identification of BSE in the UK 1986, the US has taken a series of steps to prevent the entry of the disease into the US or the propagation of the disease if it occurred. All of the precautions against BSE taken by the US have been science-based, targeting known

risks. These prevention strategies have been successful to date, in that no BSE has been diagnosed in the US.

Opportunities for Strengthening Safeguards

Ignorance, complacency and lack of resources are the three greatest threats to the prevention of BSE and rapid diagnosis and response if it occurs. Precautions taken to preclude BSE from the US must be regularly re-evaluated and enhanced when new science becomes available or weaknesses in the current system are identified. Documentation of our BSE status and rapid response to any potential BSE occurrence depends on an aggressive surveillance system. While the US has the strongest surveillance system outside of Europe, the identification and testing of high risk cattle populations must be expanded. Testing of a broader sample of older cattle will strengthen our surveillance system. The testing also needs to target older cattle dying on the farm and debilitated animals that are euthanized or presented for slaughter. No additional surveillance benefit would be gained by testing of routine slaughter cattle, however. Most cattle in the US are slaughtered before 24 months of age, which is too young to detect the disease even if these had been exposed. The most efficient and effective surveillance targets the high risk populations, ie, cattle imported from Europe and US cattle greater than 3 years of age which have been potentially exposed to feeds containing rendered ruminant protein. In terms of risks, the greatest remaining potential risk for animal or human exposure to BSE is cattle brain and spinal cord, the two tissues containing the highest infectivity in BSE affected cattle. Removal of brain and spinal cord from the raw material stream for rendering and from the human food supply would provide one additional safeguard against BSE. Continued education of animal producers, agribusiness and consumers represent a key component of the prevention program. The producer and consumer play an important role in managing risk. Finally, the US lags behind Europe in diagnostic laboratory capabilities and research dollars directed toward BSE. Futhermore, the animal health infrastructure in the US has eroded over the past two decades, reducing our potential for prevention, rapid detection and response.

Conclusion

The US has implemented a series of prevention measures that have kept BSE out of the US to date and created a series of safeguard to protect the American cattle herd and consumer if BSE should occur here. Surveillance, regulatory actions and voluntary initiatives taken by the US Department of Agriculture, Food and Drug Administration, animal producers and agricultural industries have all contributed to this prevention effort to date. The future adequacy of the precautions taken by the US must rely on the latest science available. As new risks are identified, the US must respond quickly to strengthen the surveillance system, and if warranted, implement additional prevention measures. The conundrum of prevention is that, if it is successful, then people will ask why monies were spent on something that never occurred. On the other hand, if BSE occurs in the US, people will ask why more prevention measures were not taken. Given the insidious nature of this disease and its widespread ramifications for animal

and human health, I would argue on the side of aggressive prevention. Protecting America's livestock populations is the first line of defense against BSE.